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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/750,779	01/02/2001	Wei-ping Li	12013/55202	7468

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KENYON & KENYON
ONE BROADWAY
NEW YORK, NY 10004

EXAMINER
NGUYEN, DAVE TRONG

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 08/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/750,779	LI ET AL.	
	Examiner	Art Unit	
	Dave Nguyen	1632	

-- Th MAILING DATE of this communication appears on the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-46* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *detailed action* .

Election/Restriction

Group Restriction is required under 35 U.S.C. 121 as follows:

Claims 6-9, 15-18, 24-27, 33-36, 43-44, are generic or linked to a plurality of **disclosed patentably distinct inventions** drawing to a medical device comprising:

A specifically named therapeutic agent as listed in the claims.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed invention as set forth above even though this requirement is traversed.

Should the invention drawn to a medical device comprising a DNA encoding "such agents" be elected, the elected invention is also generic or linked to plurality of **disclosed patentably distinct inventions** drawing to a medical device comprising a DNA encoding a particularly named agent as listed in the linking claims.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed invention as set forth above even though this requirement is traversed, *e.g.,* a specifically named DNA that encodes a product that must possess a specifically named therapeutic activity as listed in the linking clams.

Claims 6, 15, 24, 33, 43 link all of the inventions drawn to each of specifically named and listed therapeutic agent. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s),. Upon the allowance of the linking claims, the restriction requirement as to the liked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such (claim(s) depending from or including all the limitations of the allowable lining claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler,* 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions of "therapeutic agent" containing medical devices are distinct, each from the other because of the following reasons:

:As set forth in MPEP 803.02unity of invention for exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. The listed therapeutic agent do not have unity of invention because not only a specifically common utility is not shared by the therapeutic agents, each of the therapeutic agents do not share any substantial structural feature disclosed as being essential to that utility of the specifically intended or named therapeutic agent. Furthermore, issues regarding patentability of gene therapy methods of employing any DNA encoding a cholesterol lowering agent are not necessarily the same as gene therapy methods of employing any DNA encoding an angiogenic protein, when used in the context of the claimed invention. Likewise, the polynucleotide encoding "such agents" do not have the unity of the invention because of the same reasons set forth above.

Species Restriction is also required under 35 U.S.C. 121 as follows:

Claims 4, 13, 22, 31, 41, are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named cationic polyelectrolyte as listed in the claims.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as listed above even though this requirement is traversed.

Claims 5, 14, 23, 32, 42, are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named medical device as listed in the claims.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as listed above

even though this requirement is traversed.

Claims 6-9, 15-18, 24-27, 33-36, 43-44, are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named therapeutic agent as listed in the claims.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as listed above even though this requirement is traversed.

Claims 37 and 46 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named tissue as listed in the claims.

Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species as listed above even though this requirement is traversed.

Should applicant traverse on the ground that the species as indicated above are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because of the patentably distinct inventions and/or species as listed above, it would be unduly burdensome for the examiner to search and examine all of the subject matter being sought in the presently pending claims, and thus, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently

named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst Dianiece Jacobs, whose telephone number is **(703) 305-3388.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051.**

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is **(703) 305-7401**.

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen
Primary Examiner
Art Unit: 1632

DAVE T. NGUYEN
PRIMARY EXAMINER

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